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OBJECTIVES: In economic evaluations in oncology, survival data is typically extrapolated without taking into account prognostic factors. If individual level trial data are available, patient and disease characteristics observed at baseline are considered. However, survival models typically disregard information that are not known at baseline, e.g. response to treatment, but that may be valuable for the prognosis of patients and hence for decision making. In this study we present a parametric survival model that included response to treatment over time. **METHODS:** Data from 99 patients with late-stage soft tissue sarcoma from a clinical trial was used. Survival information and the percentage change in the sum of the longest diameters of target lesions (i.e. the basis for response evaluation) measured repeatedly during follow-up were utilized. A joint model was estimated linking a random effects sub-model for the change of tumor size with a Weibull sub-model for the survival outcome. The association between change of tumor size over time and overall survival was assessed. Several different functional forms were explored to model the tumor size data and the best fitting model was selected. **RESULTS:** The median follow-up time in the trial was 1.6 years; 63 patients died. On average, 4.8 measurements on tumor size were available per patient. A flexible cubic B-spline sub-model provided the repeatedly measured tumor size change data the best model fit. The association between tumor growth and overall survival was marginally statistically significant with a P value of less than 0.10. **CONCLUSIONS:** The presented joint model demonstrated that response to treatment over time may be important to consider when building survival models for health economic evaluations in oncology. The model explicitly incorporated the heterogeneity of patients not observed at baseline providing a clinically relevant survival model. Individual survival predictions can be prepared using patient-specific history of tumor growth.

RESEARCH ON METHODS – Patient-Reported Outcomes Studies

PRM135

ASSESSMENT OF THE HUNTINGTON QUALITY OF LIFE INSTRUMENT (H-QOL-I) CROSS-CULTURAL VALIDITY

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OBJECTIVES: The Huntington Quality of Life Instrument (H-QoL-I) is the first self-reported specific instrument developed to assess the health-related QoL (HRQoL) of patients with Huntington's disease (HD). It includes three subscales: motor (4 Likert-type items), psychology (4 Likert-type items) and socializing (3 Likert-type items). The aim of the study was to assess whether patients from different countries respond differently to the H-QoL-I instrument. **METHODS:** Data were from the European study of HD burden (EURO-HDB) survey and included data across 6 countries: France, Germany, Italy, Spain, Poland and the USA. The Differential Item Functioning (DIF) method was adopted to examine whether patients from different countries with the same characteristics had different probability of giving a certain response on H-QoL-I. An item was considered as displaying a DIF if the p-value associated with the two-degree-of-freedom Chi-squared test comparing the two ordinal logistic regressions (with/without country effect and an interaction term between the total rest score and country) was lower than 0.01 and the Zumbo-Thomas effect size was higher than 0.130. Zumbo-Thomas effect size measure and associated p-value were calculated for each item and for all pairs of countries (i.e. 15 combinations). **RESULTS:** The study included 633 patients (176 French, 124 Italian, 44 German, 60 Polish, 59 Spanish and 170 American). No DIF was detected across all combinations of countries for all items. Sixteen pairwise Zumbo-Thomas effect size measures referring to 7 items were found significant but were lower than 0.130. **CONCLUSIONS:** This study did not detect any variation across the studied countries in the assessment of HRQoL of HD patients using the H-QoL-I instrument. These results support the cross-cultural validity of the H-QoL-I.

PRM136

ASSESSMENT OF THE HUNTINGTON CLINICAL SELF-REPORTED INSTRUMENT (H-CSRI) CROSS-CULTURAL VALIDITY

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OBJECTIVES: The H-CSRI is the first clinimetric self-reported instrument for patients with Huntington's disease (HD). It includes three subscales: motor (13 Likert-type items in 4 dimensions), functional (7 Yes/No questions) and behavioural (13 Likert-type items in 4 dimensions). The aim of the study was to assess whether patients from different countries respond differently to H-CSRI. **METHODS:** Data were from the European study of HD burden (EURO-HDB) survey and included data across 6 countries: France, Germany, Italy, Spain, Poland and the USA. The Differential Item Functioning (DIF) method was adopted to examine whether patients from different countries with the same characteristics had different probability of giving a certain response on H-CSRI. An item was considered as displaying a DIF if the p-value associated with the two-degree-of-freedom Chi-squared test comparing the two ordinal logistic regressions (with/without country effect and an interaction term between the total rest score and country) was lower than 0.01 and the Zumbo-Thomas effect size was higher than 0.130. Zumbo-Thomas effect size measure and associated p-value were calculated for each item and for all pairs of countries (i.e. 15 combinations). **RESULTS:** The study included 633 patients (176 French, 124 Italian, 44 German, 60 Polish, 59 Spanish and 170 American). Almost all the items (24 of 26) didn't show any cross/cultural difference. The two items showing DIF were related to the dimension "precise movement" and were detected in the Spain-Italy comparison (ΔR^2 [left hand] =0.2165, ΔR^2 [right hand] =0.1618) and in the Spain-France comparison (ΔR^2 [left hand] =0.1571, ΔR^2 [right hand] =0.1578). **CONCLUSIONS:** Globally, these data support the H-CSRI cross-cultural validity. Further analyses should be conducted to confirm if those particular items need to be revised in the Spanish version.

PRM137

SEVERITY AND FUNCTIONAL DISABILITY OF PATIENTS WITH OCCUPATIONAL CONTACT DERMATITIS: VALIDATION OF THE GERMAN VERSION OF THE OCCUPATIONAL CONTACT DERMATITIS DISEASE SEVERITY INDEX (ODDI)

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OBJECTIVES: The Occupational Contact Dermatitis Disease Severity Index (ODDI) was designed in Australia to measure severity and functional disability in patients with occupational contact dermatitis (OCD) of the hands. The psychometric properties of the German version of the ODDI are unclear. Our objective was to investigate the validity and reliability of the German ODDI version. **METHODS:** The ODDI was translated and linguistically validated into German for Germany, following industry standard procedures of concept definition, dual forward translation, back translation and reconciliation, and clinician review. Once the German version was available, data was drawn from the baseline assessment (T0) and first follow-up (T1) of the German chronic hand eczema (CHE) registry (carpe). Spearman correlations of the ODDI with reference measures were computed to assess validity. Cronbach's alpha was calculated as a measure of internal consistency and the intraclass correlation coefficient (ICC) to assess retest-reliability. Smallest real difference (SRD) and minimal clinical important difference (MCID) were calculated to assess sensitivity to change. Physician Global Assessment (PGA) was used as an anchor for the MCID. **RESULTS:** 422 patients (54.5% female, mean age: 45.1 years) were included for analysis. Cronbach's α was found to be 0.73. The ICC was 0.79. Correlations of the ODDI total and the Dermatology Life Quality Index (rho=0.36) as well as the PGA (rho=0.48) and patient-assessed disease severity (rho=0.40) were of moderate strength. The MCID (1.29) was found to be smaller than the SRD (1.87). **CONCLUSIONS:** The German ODDI version is reliable and valid to measure functional impairment and disease severity in patients suffering from OCD. The MCID falls within the range of measurement error and should not be used.

PRM138

MAPPING FACT-P TO EQ-5D IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC): PERFORMANCE OF A PREVIOUSLY DEVELOPED ALGORITHM WHEN APPLIED ON A SAMPLE WITH A DIFFERENT DISEASE STAGE

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OBJECTIVES: To evaluate the predictive performance of a previously published mapping algorithm for converting the prostate cancer specific instrument FACT-P (Functional Assessment of Cancer Therapy–Prostate) to EQ-5D utility values (UK tariff) on a sample with a different disease stage than the one on which the model was generated [Skaltsa et. al. ViH 2014]. **METHODS:** We applied a previously developed algorithm to the data obtained from a randomized, double-blind, placebo-controlled phase 3 trial in asymptomatic/mildly symptomatic chemo-naïve mCRPC patients. The trial collected EQ-5D and FACT-P data at baseline and until treatment discontinuation. The mapping model was developed on mCRPC patients in a post-chemo setting, included the FACT-P subscale scores and baseline variables and used separate algorithms for patients with good and poor health defined as a FACT-P score exceeding or not 76. Model performance was assessed by mean absolute error (MAE) and root mean squared error (RMSE). **RESULTS:** The testing dataset contained 1,669 patients with baseline and $\geq$1 post-baseline scores. The average baseline EQ-5D utility and FACT-P total score were 0.844 and 119.5 respectively. Percentage of perfect health was 37% across all visits (ceiling effect). The average (across all visits) observed and predicted EQ-5D utility index value was 0.823 and 0.842, respectively. The model yields accurate predictions (MAE=0.107; RMSE=0.150) comparable to the ones obtained on the development sample (MAE=0.117; RMSE=0.162). The model predicts well for milder health states, but overpredicts for the more severe ones (EQ-5D utility$\leq$0.5: MAE=0.436, RMSE=0.258; EQ-5D utility > 0.5: MAE=0.096, RMSE=0.125). **CONCLUSIONS:** Although external validation is recommended using similar samples, our findings show that the algorithm developed in the post-chemo setting performed well in a pre-chemo setting in mCRPC patients, although overpredicts for severe states. This model seems suitable for predicting utility values for economic evaluation when a preference-based measure is absent in chemo-naïve mCRPC populations.

PRM139

HOW DO INDIVIDUALS COMPLETE THE CHOICE TASKS IN A DISCRETE CHOICE EXPERIMENT?

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